

510(k) Summary

Submitted By:

Karen Bradburn, RAC
Senior Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, PO Box 489
Bloomington, IN 47402
812-339-2235

K070410

APR 27 2007

Device:

Trade Name:	Cook MicroWire Wire Guide
Proposed Classification:	Wire, Guide, Catheter
	21 CFR §870.1330

Indications for Use:

The Cook MicroWire Wire Guide is indicated for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

Predicate Devices:

The Cook MicroWire Wire Guide is similar in terms of intended use, materials of construction and technological characteristics to predicate devices reviewed as devices for facilitating delivery of percutaneous catheters into the cardiovascular system.

Device Description:

The Cook MicroWire Wire Guide is manufactured using a nitinol mandril with a PTFE coating and a stainless steel and palladium distal tip. The maximum outside diameter is 0.0142-inch and will be available in 135, 190 and 300 cm lengths. It will be supplied sterile, intended for one-time use.

Substantial Equivalence:

The Cook MicroWire Wire Guide is similar to many devices in commercial distribution for facilitating delivery of percutaneous catheters into the cardiovascular system. The identical indications for use, principles of operations, similar materials of construction and technological characteristics of the wire guide support a determination of substantial equivalency.

Test Data:

The Cook MicroWire Wire Guide was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

1. Tensile Test
2. Tip Flexibility Test
3. Fracture Test
4. Flexing Test
5. Torque Strength Test
6. Torque Response Test
7. Biocompatibility Testing
8. Bioburden Testing
9. Endotoxin Testing
10. EtO Residual Testing

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a wire guide.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cook Incorporated
c/o Ms. Karen Bradburn
Senior Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

APR 27 2007

Re: K070410
Cook MicroWire Wire Guide
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II (two)
Product Code: DQX
Dated: April 6, 2007
Received: April 9, 2007

Dear Ms. Bradburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

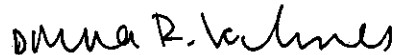
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K070410

Device Name: Cook MicroWire Wire Guide

Indications for Use:

Indicated for use in facilitating delivery of percutaneous catheters into the cardiovascular system.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James R. Valmeyer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070410